

**DOCKET NO.: TJU-2389
PATENT APPLICATION**

**SERIAL NO.: 09/819,252
FILED: MARCH 27, 2001**

REMARKS

Status of the claims

Claims 1-33 are in the application.

Claims 1-24, 28, 32 and 33 have been withdrawn from consideration.

Claims 25-27 and 29-31 have been rejected.

By way of this amendment, claims 1-24, 26, 28, 30, 32 and 33 have been canceled and claims 25, 27, 29 and 31 have been amended.

Upon entry of this amendment, claims 25, 27, 29 and 31 will be pending.

Summary of the amendment

Claims 1-24, 26, 28, 30, 32 and 33 have been canceled as being directed at non-elected inventions.

Claims 26 and 30 have been canceled as being duplicative of amended claims 25 and 29, respectively.

Claims 25 and 29 have been amended to delete reference to non-elected aspect of the invention relating to detection of translation product. No new matter has been added.

Rejection under 35 U.S.C. §112, first paragraph

Claims 25-27 and 29-31 have been rejected under 35 U.S.C. §112, first paragraph, as

containing subject matter which was not described in the specification in such a way to enable one skilled in the art to which it pertains, or to which it is most nearly connected, to make and/or use the invention. It is asserted that the claimed invention is not enabled because the level of unpredictability in the art. Applicants respectfully disagree and urge that the claims are in compliance with the first paragraph of 35 U.S.C. §112.

Mallo (1997) is cited in support of the rejection. Mallo reports experiments indicating a decrease in CDX2 expression levels in a human colorectal cancer cell line and no detectable levels of CDX2 in other tissue including stomach tissue. It is asserted that these data demonstrate the general state of the art and the level of predictability of diagnosing stomach and esophageal cancer by detecting the expression of CDX2 in tissue.

Applicants respectfully urge that Mallo does not support the enablement rejection of the pending claims but rather Mallo is consistent with and supports the patentability of the claimed invention. The data in Mallo with respect to CDX2 expression levels in a human colorectal cancer cell line do not raise any scientific basis to doubt the asserted utility of using CDX2 as a marker for stomach and esophageal cancer. The data with respect to the lack of CDX2 expression in tissues such as stomach is consistent with and supports the asserted utility of the invention.

The enablement requirement of 35 U.S.C. §112 is satisfied so long as a disclosure contains sufficient information that persons of ordinary skill in the art having the disclosure

before them would be able to make and use the invention. *In re Wands*, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988) (the legal standard for enablement under section 112 is whether one skilled in the art would be able to practice the invention without undue experimentation). In this respect, the following statement from *In re Marzocchi*, 169 U.S.P.Q. 367, 369-370 (C.C.P.A. 1971), is noteworthy:

The only relevant concern of the Patent Office under these circumstances should be over the truth of any such assertion. The first paragraph of § 112 requires nothing more than objective enablement. How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is of no importance.

As a matter of Patent Office practice, then, a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirements of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied upon for enabling support. (Emphasis added)

Any assertion by the Patent Office that an enabling disclosure is not commensurate in scope with the protection sought must be supported by evidence or reasoning substantiating the doubts so expressed. *In re Dinh-Nguyen*, 181 U.S.P.Q. 46 (C.C.P.A. 1974); *In re Bowen*, 181 U.S.P.Q. 48 (C.C.P.A. 1974).

Mallo has been offered as evidence that demonstrates unpredictability by referring to data showing CDX2 expression levels in human colorectal carcinoma and normal tissue. These data

do not support a questioning of the objective truth of Applicants' assertion that the claimed invention is enabled. The claimed invention relates to diagnosis of esophageal and gastric cancers. Reference to CDX2 expression levels in colorectal cancer cells fails to establish any basis to doubt Applicants assertion that CDX2 expression can be used as a marker for esophageal and gastric cancers. The data in Mallo provide no basis to question the objective truth Applicants assertion that the **claimed invention** is enabled. The data in Mallo, however, do provide a basis to **accept** the objective truth of Applicants assertion that the **claimed invention** is enabled. Specifically, the data indicating that lack of CDX2 expression in stomach tissue supports its use as a marker for stomach cancer.

Applicants respectfully urge that Mallo does not provide the requisite evidence needed to question the objective truth of Applicants assertion that the claimed invention is enabled. In the absence of such evidence, the objective truth of Applicants assertion that the claimed invention is enabled must be accepted. Mallo does not support the rejection of the claims but in fact supports their patentability. Applicants respectfully request that the rejection be withdrawn.

Conclusion

Claims 25, 27, 29 and 30 are in allowable form. A Notice of Allowance is earnestly solicited.

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Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version with markings to show changes made."

Respectfully submitted,



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS

Claims 1-24, 26, 28, 30, 32 and 33 have been canceled.

Claims 25, 27, 29 and 31 have been amended as follows.

25 (Amended). A method of diagnosing an individual who has stomach cancer comprising the steps of examining a sample of stomach tissue to detect the presence of CDX2 transcript [or translation product] wherein the presence of CDX2 transcript [or translation product] in a stomach sample indicates stomach cancer.

27 (Amended). The method of claim 25 [26] wherein the presence of CDX2 gene transcription product is determined by polymerase chain reaction wherein said sample is contacted with primers that selectively amplify CDX2 gene transcript or cDNA generated therefrom.

29 (Amended). A method of diagnosing an individual who has esophageal cancer comprising the steps of examining a sample of esophagus tissue to detect the presence of CDX2 transcript [or translation product] wherein the presence of CDX2 transcript [or translation

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product] in an esophageal sample indicates esophageal cancer.

31 (Amended). The method of claim 29 [30] wherein the presence of CDX2 gene transcription product is determined by polymerase chain reaction wherein said sample is contacted with primers that selectively amplify CDX2 gene transcript or cDNA generated therefrom.